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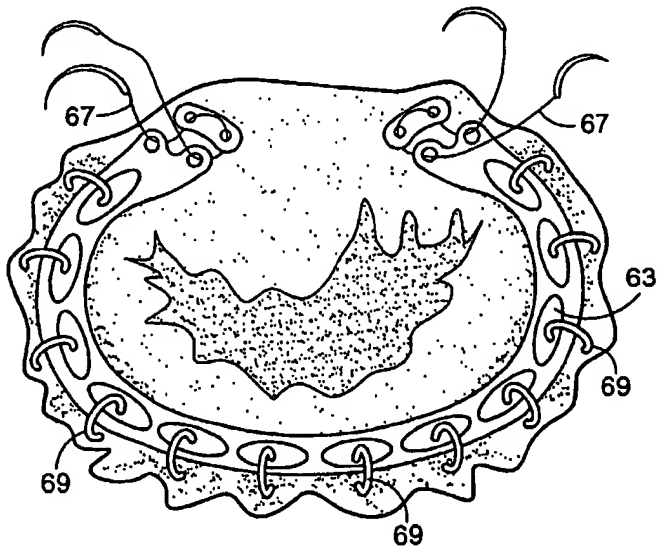

(57) Abstract: A system method for reconfigurating an atrioventricular heart valve. The system comprises a partial or complete annuloplasty ring (13, 43, 51, 61) having a size and shape proportioned to reconfigure a heart valve of a patient that has become in some way incompetent, a pair of trigonal sutures (67) or implantable anchors, and a plurality of staples (69) having pairs of legs that are sized and shaped for association with the ring at spaced locations along the length thereof. The system permits relative axial movement between the staples (69) and the ring, whereby a patient's heart valve can be reconfigured in a manner that does not deter subtle shifting of the native valve components. Staples may be made of a shape-memory alloy material and may have legs that have free ends that form an interlocking orientation following implantation Annuloplasty ring may be a complete or partial ring and may be fenestrated having a plurality of spaced-apart elongated windows (63). A partial ring may have a pair of aligned holes at one end which fit over posts of anchors. An alternate method routes a flexible wire which may be of shape-memory material through the bights of pre-implanted staples and permits adjustment of the effective length of a partially installed ring.

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IMPLANTATION SYSTEM FOR ANNULOPLASTY RINGS

Field of the Invention

This application claims priority from U.S. Provisional Application Serial No. 60/342,824 filed Dec 21, 2001.

This invention relates to prosthetic annuloplasty rings designed to surgically correct defects in heart valves and more particularly to systems for the efficient and effective implantation of such corrective rings.

Background of the Invention

Rheumatic, connective tissue or ischemic heart diseases may heavily affect the configuration of the atrioventricular heart valves. Diseased valves may become narrow, incompetent or both. A great many patients suffering from ischemic heart disease, who previously underwent myocardial infarctions, consequently develop various degrees of mitral valve incompetence. Typically in those patients, the valve may grossly seem to be normal; yet its annulus is dilated, causing coaptation or interengagement of the leaflets to be disturbed and resulting in incompetence of the valve. Such patients will benefit from an annuloplasty as a repair, either alone or in addition to a revascularization procedure, i.e. coronary artery bypass surgery. Most but not all mitral and tricuspid valves are amenable to reconstruction, and the etiology of valvular disease has an important bearing on the indication for repair. A rheumatic valve is probably the most difficult to conserve; conversely, degenerative valves with thin and redundant tissue, elongated or ruptured chordae, and/or a dilated annulus are very likely to be repairable. Ischemic regurgitation can often be repaired with annuloplasty.

Annuloplasty rings have now become essential components of reconstructive surgery of the mitral and tricuspid valves. Their safety and durability have been proven in numerous clinical studies that have occurred since their genesis in the late 1960's when Dr. Alain Carpentier introduced the prosthetic ring. This completely rigid ring had the systolic shape of the mitral and tricuspid valve; once sutured in place, the ring permanently stabilized the valve annulus into this shape. He designed a series of multi-sized fabric-covered rings with a stainless steel or a titanium core, which were configured to approximate the original shape of the diseased or dysfunctional valve annulus. Multiple sutures were sewn around the periphery of the annulus creating an entire circle of guide lines. The ring was positioned on the valve annulus, and the guide lines were

then attached to the ring and used to draw the valve opening to the configuration of the ring (which would be the approximate shape of the original valve annulus). Although Dr. Carpenter's method could significantly improve valve function, some surgeons believe that the rigid structure of rings of this type may compromise the natural flexibility of the valve components. An open or partial ring annuloplasty prosthesis is described in U.S. Patent No. 4,164,046; it discloses a uniquely shaped open ring useful for mitral and tricuspid annuloplasty having a special velour exterior.

Subsequent experimental and clinical echocardiographic studies showed that the mitral and tricuspid annuli change continuously in size and shape during the cardiac cycle. These results induced Dr. Carlos Duran, in 1975, to develop a completely flexible ring that could adapt to such changes. His fully flexible annuloplasty ring could only be shortened in the posterior segment by the placement of placating sutures; however, judgment of the position, size and spacing of these sutures requires skill and experience. Other adjustable annuloplasty rings are described in U.S. Patent Nos. 4,042,979 and 4,290,151. Another type of flexible ring design is shown in Patent No. 5,450,860 which includes an open ring in the form of a wide, flexible ligament that is implanted into the valve annulus. The ligament is typically made of expanded polytetrafluoroethylene to provide flexibility, promote tissue ingrowth and allow sutures to readily pass therethrough.

Although flexible rings may avoid constraining the natural flexibility of the annulus while still improving valve function, there are some disadvantages in using flexible rings. For example, when the suture spacing along the annulus is not matched to the spacing on the ring, tension in the tissue may result and cause tissue puckering. Loss of annulus flexibility may also occur over time should scarring and stiffening of the valve annulus develop as a result of the large number of sutures needed, and such may result in a valve physiology that is similar to that of a rigid ring, somewhat compromising the natural flexibility of the valve.

Studies were also done as to determine whether these flexible annuloplasty rings would entirely correct the problems witnessed with regard to annuloplasty rings in general. As a result, it is believed that such a flexible ring may lower the risk of dehiscence because of reduced tension on sutures that would otherwise occur during systole, and such may also reduce the negative consequences of somewhat inaccurate

placement of annuloplasty ring sutures, which could result in malrotation of the ring. It is also felt that such may minimize the risk of systolic anterior motion (SAM) when a left ventricular outflow tract obstruction occurs, which is a potential and fairly frequent complication associated with the use of a completely rigid ring in the mitral position. However, they still have not proved to be a complete solution to these problems.

With the improvements in cardiopulmonary bypass and myocardial protection on one hand and in life expectancy on the other hand, an increase in interest in valve reconstructions and demand for improved novel technologies is foreseen. With careful patient selection, valve reconstruction should exhibit significant benefits compared with valve replacement, to wit: (1) decreased operative mortality and late mortality rates; (2) improved hemodynamics due to better preservation of left ventricular function; (3) fewer thromboembolic complications and reduced risk anticoagulant-related hemorrhage, particularly when compared with the installation of mechanical prostheses; (4) reduced risk of infected endocarditis; (5) greater durability leading to lower percentage of reoperations; and (6) reduced operating costs.

In summary, the prevailing techniques that are now used throughout the world, without resorting to a full valve replacement, generally employ an annuloplasty ring to reduce a great part of the circumference of the valve. This is accomplished by suturing into place an elastic, semi-rigid or rigid ring that is smaller than the native annulus being reduced; the ring may be of a closed shape or an open band or C-shape. Installation takes place using regular sutures, in much the same manner as when a full valve replacement is carried out, and the procedure may consume as much time as a full valve replacement, for example, an average of about 35 to 45 minutes. Accordingly, improved annuloplasty systems and methods of reducing this time of surgery have continued to be sought.

Summary of the Invention

The invention provides an implantation system and a method for implanting annuloplasty rings which not only can be accomplished in a reduced time period but which is effective to achieve better coaptation of the leaflets following implantation. The system results in improved hemodynamic functioning and substantially eliminates the risk of over-correction. Staples are employed to affix the prosthesis to the patient's valve annulus in a manner to allow relative movement axially of the ring.

Such an implantation system may employ especially designed staples to implant an annuloplasty ring that may be of essentially any design, open or closed, and the intention is to replace all the sutures previously used but the two trigonal sutures. Such staples can be delivered through a pistol-like applicator of the type generally used for surgical stapling to close wounds and the like. In one embodiment, the staples are initially implanted to provide a well defined and easily installed pathway through which a flexible annuloplasty device can be routed and then ultimately secured in place by ligation to the two trigonal sutures. In other embodiments, staples are used to implant a ring or a partial or open ring of current design or to implant a fenestrated partial ring, that has been prepositioned in desired orientation on the patient's annulus.

In one specific aspect, the invention provides a method of reconfiguring an atrioventricular heart valve, which method comprises providing an annuloplasty ring sized and shaped to have a desired configuration, and implanting said ring at the mitral or tricuspid valve of a patient by implanting a plurality of staples having pairs of legs in the patient's heart tissues so as to spatially position said annuloplasty ring in a reconfiguration association therewith, while allowing the tissue in which said staples are implanted to have the ability to shift axially with respect to said ring.

In another specific aspect, the invention provides a system for reconfigurating an atrioventricular heart valve, which system comprises a partial or complete annuloplasty ring having a size and shape proportioned to reconfigure a heart valve of a patient that has become in some way incompetent, a pair of pledgetted trigonal sutures, and a plurality of staples having pairs of legs that are sized and shaped for association with said ring at spaced locations along the length thereof in a manner that permits relative axial movement of said ring, whereby a patient's heart valve can be reconfigured in a manner that does not deter subtle shifting of the native valve components.

Brief Description of the Drawings

FIG. 1 is a top perspective view showing a mitral valve with a pair of trigonal sutures extending from the commissures thereof.

FIG. 2 is a plan view of an annuloplasty ring that might be associated with the valve of FIG. 1 to reconfigure it.

FIG. 3 is a perspective view similar to FIG. 1 with the annuloplasty ring similar to that shown in FIG. 2 located in desired association with the native annulus of the

patient's valve, with the two trigonal sutures extending through a fabric covering of the ring.

FIG. 4 is a view similar to FIG. 3 showing the annuloplasty ring stapled in secure position.

FIGS. 5, 5A and 6 are front views of three different staples that might be employed to complete the implantation of the annuloplasty ring to the tissue of the patient.

FIG. 5B is a side view of the staple shown in FIG. 5A.

FIGS. 6A and 6B are perspective views of two additional styles of staples which might alternatively be used.

FIG. 7 is a view similar to FIG. 1 showing a tricuspid valve with two trigonal sutures in place.

FIG. 8 is a view similar to FIG. 3 with a flexible annuloplasty partial ring associated with the valve of FIG. 7.

FIG. 9 is a view similar to FIG. 8 showing the partial annuloplasty ring stapled into place with the trigonal sutures ligated thereto.

FIG. 10 is a view similar to FIG. 1 showing a mitral valve with a partial annuloplasty ring in place and with the ends thereof associated with the trigonal sutures.

FIG. 11 is a plan view of a single wire partial annuloplasty ring schematically illustrating the preferred systematic placement of staples in association therewith.

FIG. 12 is a plan view of a fenestrated partial annuloplasty ring.

FIG. 13 is a view similar to FIG. 10 showing the fenestrated partial ring of FIG. 12 stapled in position with its ends ligated to the trigonal sutures.

FIG. 14 is a view similar to FIG. 1 of a mitral valve showing a pattern of staples implanted from commissure to commissure along a section of the native ring of the diseased mitral valve.

FIG. 15 is a schematic view showing a needle attached to the lead end of a flexible annuloplasty band disposed in a sheath and ready to be routed from one commissure to the other through the pattern of implanted staples, with the tail band being shown connected to the ends of the left-hand trigonal suture.

FIG. 16 is a perspective view of the valve of FIG. 14 with the partial annuloplasty band of FIG. 15 located in place and with the sheath removed to show a pair of flexible wires, the ends of which are ligated to the respective trigonal sutures.

FIG. 17 is a perspective view of an anchor that can be used with an alternative system embodying various features of the invention.

FIGS. 18 and 19 show two partial annuloplasty rings that may be employed as part of such system along with the anchor posts shown in FIG. 17.

FIGS. 20 and 21 are schematic perspective views showing the installation of a system incorporating a wire annuloplasty ring similar to that illustrated in FIG. 19.

FIGS. 22 and 23 are perspective views illustrating the system depicted in FIG. 20 using an alternative shape-alloy memory staple.

Detailed Description of the Preferred Embodiments

It has been found that, through the use of staples, preferably staples of a preferred design, an improved annuloplasty system can be created that can be installed, with the use of only two U-shaped, pledgetted trigonal sutures, in less than one-half the time it presently takes to install the present generation of annuloplasty rings. For purposes of this application, the term "annuloplasty ring" is intended to include complete generally D-shaped rings as well as open rings or bands that may have a generally C-shape and which are rigid or flexible; in any event, the annuloplasty ring that is used will be proportioned so as to reconfigure an atrioventricular heart valve that has become incompetent or in some other way defective.

Heretofore, the incorporation of an annuloplasty ring has involved an operation that generally required about as much time in surgery as an actual total valve replacement. However, using the present invention, this time can be reduced by 50% or more, thus substantially shortening the time when the patient need be on artificial life support and making surgeons more willing to use an annuloplasty procedure whenever felt feasible. Installation according to the invention can be carried out by first positioning the annuloplasty ring in association with the annulus of the valve to be reconfigured and then applying the staples, or alternatively by first implanting a series of spaced apart staples along the valve annulus to create a desired pathway for an annuloplasty ring of open configuration and then routing such a ring through the staple-defining pathway. Methods of using the first manner of implantation are hereinafter first described, followed by the second manner of implantation.

FIG. 1 shows a mitral valve having a pair of trigonal pledgetted sutures 11 extending from the commissures thereof. Pledgetted sutures which are placed at the respective commissures act both as markers which position the annuloplasty ring, and as tie-down sutures that are ligated at the completion of the implantation operation. Such are the only two sutures that are employed in implanting a closed annuloplasty ring such as the ring B shown in FIG. 2. The ring 13 has a core 15 that is suitably covered. The core 15 may be solid or may contain a coiled helical spring or the like as known in this art, if a flexible ring is desired. The ring 13 is of generally circular cross section; however, rings of different cross sections may be employed as described hereinafter. The core may be covered with a thin layer 17 of a biocompatible fabric, such as woven polyester, which fabric may optionally be associated with expanded polytetrafluoroethylene sheet material. Suture needles 18 at the opposite ends of the trigonal sutures 11 are threaded through the fabric 17 as shown in FIG. 3. The sutures are later ligated once the ring has been secured in place by attachment to the valve annulus via staples. After gauging the valve to select the proper size ring 13, the annuloplasty ring is located in association with the native annulus of the patient's valve as shown in FIG. 3, with the two trigonal sutures 11 extending through the fabric covering 17 of the ring.

Once the annuloplasty ring is positioned in contact with the annulus ring of the mitral valve to be reconfigured, it is quickly secured in the exact desired position by the implantation of staples 19, the staples in this embodiment are individually secured to the valve tissue at spaced apart locations about the entire length of the ring so as to spatially secure it radially while allowing the tissue to move axially of the ring. Surgical staples may be implanted using any suitable commercially available surgical stapler of which there are quite a variety being marketed today. Examples of such staplers include those shown in U.S. Patents Nos. 5,782,397 and 5, 918,791.

Once about 7-10 spaced-apart staples 19, which may be of any, suitable design, have been applied about the ring 13 along its entire length to secure the ring radially about the valve, as shown in FIG. 4, the two trigonal pledgetted sutures 11 are ligated to the annuloplasty ring. Ligation completes the implantation, and the entire operation will take less than one-half the time it takes to presently install a similar annuloplasty ring using a myriad of sutures as is currently common practice.

Although a variety of staples may be employed as generally known in the surgical stapling art, ceratin preferred staples are illustrated hereinafter. FIG. 5 illustrates a staple 21 having a pair of legs 23 that are formed with two inwardly protruding, opposed bends 25 which are located at the tissue surface. In their operative orientation, the legs create a portal 27 that will be located above the surface of the tissue to which the annuloplasty ring is being secured. The staple 21 will preferably reasonably closely surround the ring 13, which may be of circular cross-section, so as to effectively restrain it against movement in a radial direction while allowing free relative movement of the staple (and thus the valve tissue) along the length of the ring. Free ends 28 of the two legs 23 of the staples are customarily pointed, and they may be originally or subsequently curved at the time of implantation so as to secure the staples in the tissue. Preferably, the staples 21 are made of a shape-memory material, such as taught in U.S. Patent No. 4,485,816, the disclosure of which is incorporated herein by reference; for example, they may be made of Nitanol. For example, the staples may be originally formed in their desired closed shape and subsequently cooled below a transition temperature before deforming them into an open shape. After placement in the valve tissue, the staples 21 will revert to the closed shape, and they will be capable of generating sufficient stress to penetrate through the tissue in which they reside so that the free ends 28 assume a secure orientation. More preferably, the free ends 28 of the staples are formed so as to interlock with each other, as by providing interlocking barbs 28a, and such interlocking can be designed to occur as a result of the shape-memory material reverting to its originally formed shape. Most preferably, the staples 21 are formed of a metal material having legs 23 with flat surfaces of a substantial width. Barbs 28a protrude from facing surfaces, and the legs are designed so that the free ends will overlap each other, preferably one above the other so that the interlocking of the barbs will occur in the plane of the staple 21 itself.

FIG. 5A shows a generally similar staple 29 which might be preferred when staples are to be first implanted in spaced apart locations along the valve annulus to create a desired pathway for an annuloplasty ring of open configuration, as described hereinafter. The staple 29 has a closed upper ring section 29a that is appropriately sized to provide an opening to which an annuloplasty ring might be attached, as described hereinafter. The ring surmounts a pair of curved legs 30 which terminate in free ends similar to the barbed free ends 28 of the staples 21. To positively prevent the staple from

being driven too deeply into the tissue, a pair of oppositely extending wings 31 are provided which extend transversely outward preferably perpendicular to the plane of the staple, as best seen in FIG. 5B. The wings will engage the surface of the tissue and limit the depth of implantation of the staple to that desired. Implantation of the staples 29 would be generally similar to that of the staples 21 described above.

In the embodiment shown in FIG. 6, a staple 33 of simpler configuration is shown. The staple 33 is generally circular in shape, so proportioned to surround the perimeter of a circular cross-section annuloplasty ring, and its two spaced-apart free ends 35 are formed with barbs 37 of the type commonly found at the end of a standard fish hook. Accordingly, these staples 33 can be readily implanted using a surgical stapler of the type commonly employed; they need not be made of a shape-memory material, as they can be essentially clinched in place by standard stapling action.

Two additional staple designs having advantageous features are illustrated in perspective views labeled FIGURES 6A and 6B. Illustrated in FIGURE 6A is a staple design 121 which generally resembles staple 21 without the two interior bends 25. The staple has two free ends 123, which carry laterally extending barbs 125. The staples 121 would be similarly placed, so that the annuloplasty ring would reside in the bight of the staple and the free ends would cross. As a result of the design, the laterally extending barbs 125 would interengage, thus locking the staples in place, with the barbs embedded in the heart tissue. The staples could be made of a shape-memory material, or they could be made of a high grade stainless steel or the like and crimped by a suitable surgical stapling tool. Illustrated in FIGURE 6B is a staple 133 that generally resembles staple 33. The staple similarly has a pair of spaced apart free ends 135 that are formed with barbs 137. In this arrangement, the staples 133 are similarly placed so that the annuloplasty ring resides in the bight of the staple, but in this arrangement, one free end 135 extends in one direction and the other free end extends in the essentially opposite direction, both which directions are essentially parallel to the axis of this section of the annuloplasty ring. Again, the staples 133 can be formed from a shape-memory material, which will then inherently assume this orientation, or they may be made of stainless steel or the like and implanted using a tool which causes this particular deflection of the respective free ends.

The implantation of a partial annuloplasty ring or band in conjunction with a tricuspid valve is illustrated and described with respect to FIGS. 7-9. In FIG. 7, a tricuspid valve is shown with two double-armed 2.0 pledgetted sutures 41 pulled for

retraction. The tricuspid valve to be reconfigured is gauged, and the size of a partial ring 43 desired is determined. The two trigonal sutures 41 are then sutured to the ring 43 at the appropriate sites using suture needles 44 integrally attached to the ends thereof, and the ring 43 is lowered into association with the annulus of the valve as shown in FIG. 8. Staples 45 as described hereinbefore are radially placed around the annulus in the sequence illustrated in FIG. 11, the sequence of placement being indicated alphabetically, starting with "A". More specifically, a staple 45 is first placed at the midpoint of the ring, and then two staples 45 are placed halfway between the midpoint and each end at the "B" locations. Thereafter, additional staples 45 are placed equidistant between pairs of existing staples or between the end of the ring and the nearest staple, in two separate series, i.e. "C" and then "D", until the illustrated pattern is achieved. By placing the staples 45 in such a sequence, maximal anchoring symmetry is obtained which results in maximal coaptation of the leaflets and competent valve operation. Once all of the staples 45 are in place, both trigone anchoring sutures 41 are ligated, as depicted in FIG. 9. As should be apparent, this simplified procedure can be completed in a fraction of the time needed for traditional annuloplasty ring implantation. As a result of the procedure, the incompetent valve has been effectively reconfigured while subtle relative movement is still permitted between the stapled tissue and the annuloplasty ring in a direction axial of the ring, assuring excellent interengagement of the leaflets.

FIG. 10 illustrates a mitral valve with a partial annuloplasty ring 51 in place, similar to the one described with regard to the tricuspid valve. The pledgetted trigonal sutures 53 will be ligated to the ends of the generally C-shaped ring 51, as described hereinbefore, following placement of the confining staples 55.

FIG. 11 shows an alternative type of single wire partial annuloplasty ring 57 in combination with a pattern of staples to which reference was earlier made to describe the strategic sequential placement of staples 45 about an annulus. These staples 45 can be implanted in locations straddling the wire, or staples 29 might be used having openings in the ring sections such that the wire may be passed therethrough. Instead of attaching trigonal sutures to a fabric covering as was previously described with respect to other such rings, the single wire partial annuloplasty ring 57 is provided with a pair of ears 58 at each end which are preferably be apertured to facilitate the ligation of the trigonal sutures thereto after they are threaded therethrough. The "A" staple is placed first, followed by the two "B" staples, followed by the four "C" staples, etc.

Illustrated in FIG. 12 is a fenestrated partial annuloplasty ring 61 made of a suitable metal alloy material, e.g. titanium or Nitinol. The generally C-shaped partial

ring 61 has a plurality of elongated windows 63 running down its spine for its entire length, and a pair of apertured ears 65 are provided at each end to facilitate attachment of trigonal sutures 67 thereto. The windows 63 are proportioned so that a staple 69 can be located generally at the midpoint of each window, with one leg of the staple protruding through the window and with the staple preferably straddling the radially outer edge of the fenestrated, ring as illustrated in FIG. 13. The ring 61 can be flat, but it may advantageously be frustoconical, being disposed at an angle of about 10° to about 60° (and preferably between about 10° to about 45°) to the horizontal (i.e. to the plane which is perpendicular to the axis of the valve). Either the smaller or the larger diameter edge may be implanted closest to the valve opening, as there is great variation in the mitral valves of different patients. With the mitral valve reconstruction shown in FIG. 13, the larger diameter radially outer edge faces the valve opening. Once all of the desired staples 69 are in place, generally one with respect to each window, the pledgetted trigonal sutures 67 are ligated to the attachment ears 65 at the respective ends of the partial ring. As can be seen, the elongated windows 63 allow free relative axial movement between the edge of the fenestrated band and the staples, which are secured in the heart valve tissue. Again, the staples 69 can be any of the types depicted in FIGS. 5, 6, 6A and 6B, or they can be of the general surgical variety as it is unnecessary for them to provide a defined portal or bight-shaped to particularly surround the circumference of a circular cross-section band.

Illustrated in FIGS. 14-16 is an alternative procedure that may be used to implant a partial annuloplasty ring, which procedure is shown as being carried out to reconfigure a mitral valve, wherein a pattern of staples 71 is first placed in the valve tissue extending from commissure to commissure. More specifically, the two trigons "T" of the valve are identified, and two double-armed 2.0 pledgetted sutures 73 are placed, as in FIG. 2, and pulled for retraction. The mitral ring is identified and if necessary is pulled with the help of a skin hook. Staples 71 are then placed radially around the annulus from commissure to commissure as illustrated in FIG. 14. Staples of the style of the staples 29 may be used. The two needles of the trigonal suture 73 on the left-hand side are then threaded through holes provided in ears 75 in a connector at each end of a sheathed wire system 77 which may include one or two or more wires 79 which will have sufficient flexibility to permit them to be routed through the pathway provided by the pattern of staples 71. The wires may be made of a metal alloy or of polymeric material, and they optionally may be of a shape-memory material, such as Nitinol. Their necessary length is determined by gauging the valve, and the wire system is constructed to provide points of attachment at

the tail end, e.g. apertured ears 75, through which the two trigonal suture needles can be passed.

The leading end of the partial band system 77 is elongated to provide an introduction portion 81 at the end of the sheath which envelopes the right-hand end of the two-wire system and has a needle 83 threadably connected of its tip end. The needle 83 enables the routing of the wire system 77 between the bights of the staples 71 and the surface of the tissue in which the staples are implanted. Routing begins at the left-hand end and proceeds through the entire pathway to the opposite commissure. When the end of the wire system 77 protrudes through the last staple, the sheath portion of the system is removed to expose the pair of apertured ears 75 at the leading end and the pair of wires 79 that extend end-to-end and constitute the annuloplasty band. Once the trigonal anchoring sutures 73 are ligated to the attachment ears, the installation is complete. If the wires 79, which make up the wire system are of shape-memory material, they will then slowly assume the desired shape into which the valve is to be reconfigured, and some heating can be supplied, but should not likely be necessary. Once the heart has been closed, and the heart begins to beat on its own, the shape of the valve will steadily improve to an optimum configuration where it is fully competent.

Illustrated in FIGS. 17-22 is a further alternative procedure which obviates the need to employ a pair of pladgetted sutures for ligation at the trigons. Instead, individual anchors 85 are employed that can be quickly inserted into the tissue precisely at the targon and thereafter employed to mount the ends of an open annuloplasty ring of a type designed to permit some initial adjustment by the surgeon at the time of implantation so as to achieve the precise sizing desired. FIG. 17 shows an anchor 85 which may be employed for this purpose. The anchor includes a circular base 87 from which a pointed, barbed shaft 89 depends which is designed to become affixed in the tissue. Once the two trigons have been identified with close precision, one of these anchors is implanted at each trigone. The illustrated shaft 89 carries three barbs 91 extending outwardly therefrom and equiangularly spaced apart, e.g. by about 120°. The pointed shaft 89 protrudes into the tissue to the desired depth, with the undersurface of the circular base 87 tightly abutting the surface of the tissue, and the design of the barbs 91 is such to resist any upward withdrawal of the anchor. Carried on the upper surface of the anchor base 87 are three initially parallel rods 93 made of a shape-memory alloy such as Nitinol. In their initial configuration, the rods 93 are parallel to the shaft and are surrounded by a restraining sleeve 95 which is removable as described hereinafter. Once the two anchors

85 have been implanted, the surgeon measures the distance about the valve annulus from anchor to anchor and selects the size of an open annuloplasty ring.

Illustrated in FIG. 18 is a fenestrated ring 97 particularly designed for implantation with this anchor system. The partial annuloplasty ring 97 resembles that shown in FIG. 12, being made of similar metal, and a plurality of windows 99 run down its spine for its entire length. However, the ring has a pair of aligned circular holes 101 in each end which are sized so as to fit over the sleeve 95 which is restraining the three upstanding rods. The surgeon chooses one of the holes at each end for the initial installation and starts inserting staples along the ring using the sequential placement described hereinbefore. After the A and B staples have been installed, the surgeon checks the fit, and if it is felt that the ring is too large, the second hole 101 on one end can be placed over the anchor and the checking repeated. In the unlikely instance that it would still be too large, a further adjustment can be made by moving the other end of the fenestrated ring 97 to the second hole 101. The remaining staples are inserted, and the restraining sleeves 95 are removed from the groups of posts at each anchor. Body temperature causes the posts 93 to assume a generally C-shape bending around and over the adjacent sections of the fenestrated ring that form the perimeters of the holes 101 and securely fastening both ends to the tissue.

Illustrated in FIG. 19 is a wire ring-type annuloplasty ring 105 similar to the wire ring 67 described with respect to FIG. 11. The major difference is that apertured ears 107 at each end are axially aligned with the wire itself. Implantation of the ring is preferably carried out generally similarly to that just described; however, alternatively, staples could be initially implanted in the tissue to define the desired pathway and then one end of the wire ring threaded through the path, as previously described with regard to FIGS. 14-16. Again, once the two anchors 85 have been implanted at the precise locations of the trigons, the surgeon makes the measurement to determine the length of the ring, and a suitable wire partial ring 105 is selected and installed, as depicted in FIG. 20. For simplicity purposes, the illustrated wire ring 105' is shown as having only a single apertured ear; it should be understood that the preferred embodiments have two aligned apertured ears 107 as shown in FIG. 19 to permit adjustment. Once the wire ring is suitably aligned, barbed staples 109 are inserted at generally equal distances apart along the ring using the sequential placement procedure previously described. Once a predetermined number of staples 109 are in place, the surgeon checks the length, and if desired, shortening can be effected by repositioning one or both ends of the wire ring 105 to place the second aperture 107 from the end over the upstanding posts of the anchor 85.

Thereafter, the restraining sleeve 95 is removed, as schematically shown in FIG. 21, and the temperature causes the shape-memory alloy posts 93 to curl over the edges of the apertured ears 107, locking each ear to the upper surface of the base of the anchor.

FIGS. 22 and 23 illustrates the alternative use of barbed staples 113 made of a shape-memory alloy such as Nitinol. The staples 113, when implanted, would have the U-shape depicted in FIG. 22 in the right-hand view. The shape-memory alloy staples, upon warming to a temperature of the heart tissue, begin to slowly close as depicted in the middle view until they reach the closed configuration where the barbs interlock, as shown in the left-hand view and described hereinbefore. As depicted in FIG. 23, these shape-alloy memory staples 113 would thus securely fix the pathway for the wire ring, and once it was decided that either no adjustment was necessary to the length or once such adjustment was made by selecting a different one of the pair of apertured ears, the restraining sleeve 95 would be removed so the three parallel posts 93 shown in FIG. 23 would then automatically curl radially outward to wrap around the edges of the respective apertured ear and assume the final orientation depicted in FIG. 21.

Whereas, heretofore when it was deemed feasible to avoid replacement of a valve that had become incompetent by implantation of an annuloplasty ring, this operation has been greatly facilitated via the use of the previously described stapling procedures. By reducing the time of such phase of an operation by 50% or more, side effects of being an artificial life support are greatly lessened, and full recovery is significantly hastened.

Although the invention has been described with regard to certain preferred embodiments, it should be understood that various changes and modifications that would be obvious to one having the ordinary skill in this art may be made without departing from the scope of the invention which is defined in the claims appended hereto. For example, although only certain specific staple shapes have been illustrated, it should be understood that a wide variety of staples, made optionally of shape-alloy material, may be employed as the surgical stapling has become a well developed art. There are commercially available a number of custom designable staplers which can be employed to anchor annuloplasty rings while working at a distance of 25-35 centimeters from the annulus of a mitral valve. The disclosures of all U.S. patents mentioned hereinbefore are expressly incorporated herein by reference.

Particular features of the invention are emphasized in the claims that follow.

CLAIMS

1. A method of reconfiguring an atrioventricular heart valve, which method comprises

providing an annuloplasty ring sized and shaped to have a desired configuration, and

implanting said ring at the mitral or tricuspid valve of a patient by implanting a plurality of staples having pairs of legs in the patient's heart tissues so as to spatially position said annuloplasty ring in a reconfiguration association therewith, while providing the tissue, in which said staples are implanted, the ability to shift axially with respect to said ring.

2. The method of claim 1 wherein said ring is secured directly to the heart tissue by sutures located at the trigons of the valve.

3. The method of claim 2 wherein said annuloplasty ring is a partial ring and said trigonal sutures are respectively ligated to the opposite ends of said partial ring.

4. The method of claim 3 wherein said staples are implanted in association with said partial ring in accordance with a pattern wherein the first staple is implanted near the midpoint of said partial ring and a pair of staples are next implanted at about the halfway points between said midpoint and the respective ends.

5. The method of claim 4 wherein the remainder of the staples are respectively positioned so as to be approximately equidistant between two already implanted staples or between an already implanted staple and said end of said partial ring.

6. The method of any one of claims 1-5 wherein said staples each have a pair of inwardly protruding opposed arms that form a portal extending above the tissue surface into which the staples are implanted, said portal being sized to allow said ring to move axially therewithin.

7. The method of claim 6 wherein said staples are formed of a shape-memory material and said legs assume a secure angular orientation within the tissue following implantation.

8. The method of claim 7 wherein said legs of said staples have free ends that form an interlocking orientation following implantation.

9. The method of any one of claims 1-8 wherein said annuloplasty ring is fenestrated, being formed to have elongated windows, and wherein said staples are implanted with one leg of each extending through one of said windows.

10. The method of any one of claims 1-9 wherein said ring is secured directly to the heart tissue by anchors implanted into the upper surface of the tissue.

11. A method of reconfiguring an atrioventricular heart valve, which method comprises

implanting staples along a portion of the annulus of the mitral or tricuspid valve of a patient in a pattern extending from one commissure to an opposite commissure to provide a pathway therebetween, said staples being implanted in spaced apart locations and extending above the tissue surface so as to provide a series of open portals,

routing a flexible wire of shape-memory material through said portals so as to extend along said path from commissure to commissure, and

securing the respective ends of said wire to sutures installed in the heart tissue at each trigone,

said shape-memory alloy assuming the desired curvature to serve as a partial annuloplasty ring following implantation.

12. The method of claim 11 wherein opposite ends of said shape-memory material wire are provided with points of attachment at which said sutures are ligated.

13. A system for reconfigurating an atrioventricular heart valve, which system comprises

a partial or complete annuloplasty ring having a size and shape proportioned to reconfigure a heart valve of a patient that has become in some way incompetent,

a pair of trigonal sutures or implantable anchors, and

a plurality of staples having pairs of legs that are sized and shaped for association with said ring at spaced locations along the length thereof in a manner that permits relative axial movement between said staples and said ring,

whereby a patient's heart valve can be reconfigured in a manner that does not deter subtle shifting of the native valve components.

14. The system according to claim 13 wherein said staples each have a pair of inwardly protruding opposed arms that form a portal extending above the surface of the tissue into which the staples are implanted.

15. The system according to claim 14 wherein said staples are made of a shape-memory alloy material.

16. The system according of claim 15 wherein said legs have free ends which assume a secure angular orientation to the major length thereof following implantation in the tissue of the patient.

17. The system according to claim 16 wherein said legs have free ends that form an interlocking orientation following implantation.

18. The system according to anyone of claims 13-17 wherein said annuloplasty ring is a partial ring.

19. The system according to claim 18 wherein said partial ring is fenestrated, having a plurality of spaced-apart elongated windows.

20. The system according to claim 18 or 19 wherein a pair of anchors having shape-memory posts are included and wherein said partial ring has a pair of aligned holes at one end which are proportioned to fit over said posts and permit adjustment of the effective length of the partially installed ring.

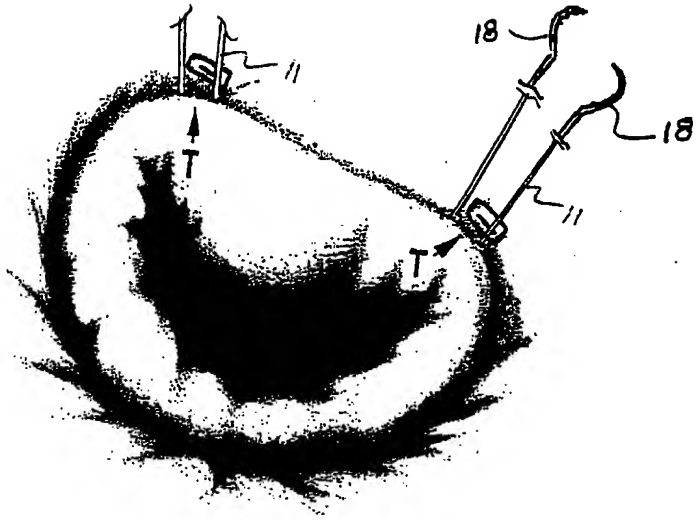


FIG. 1

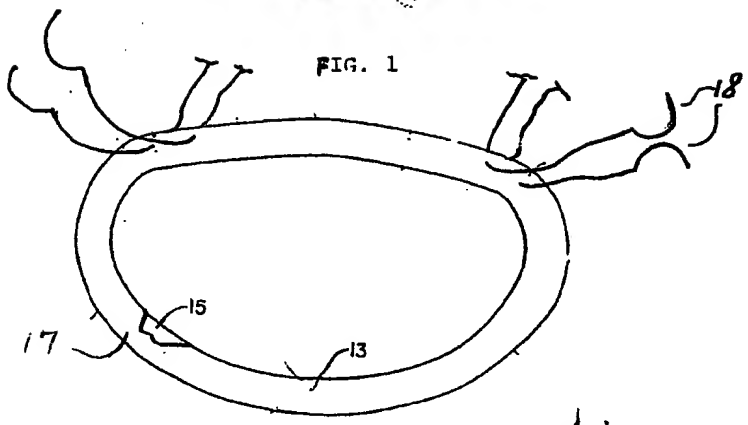


FIG. 2

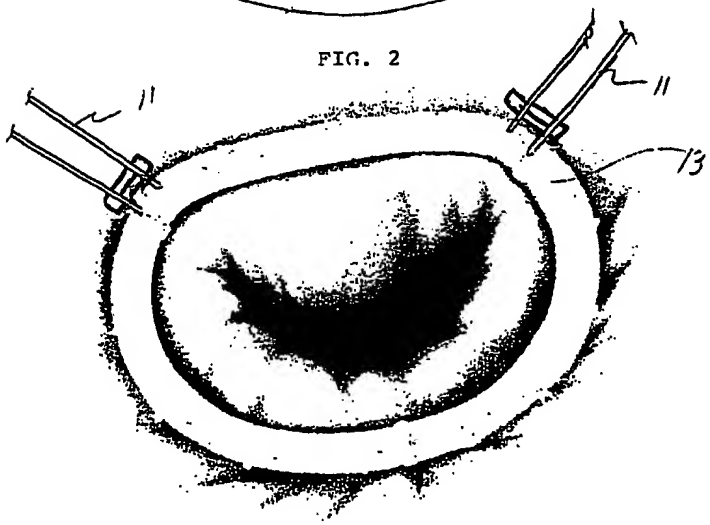


FIG. 3

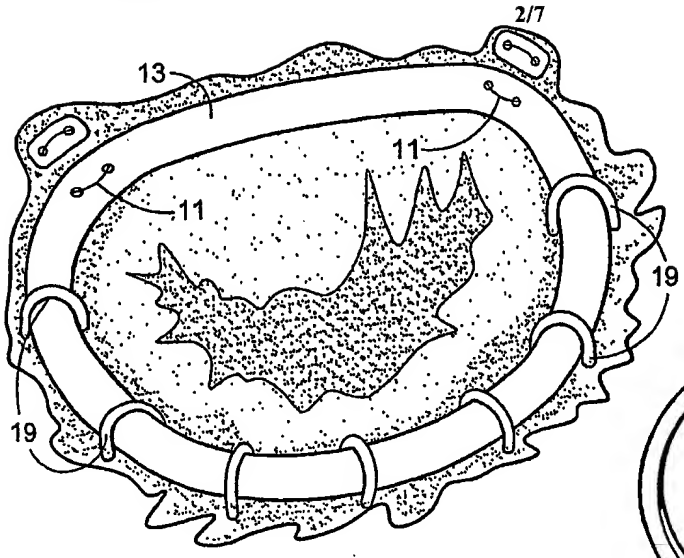


FIG. 4

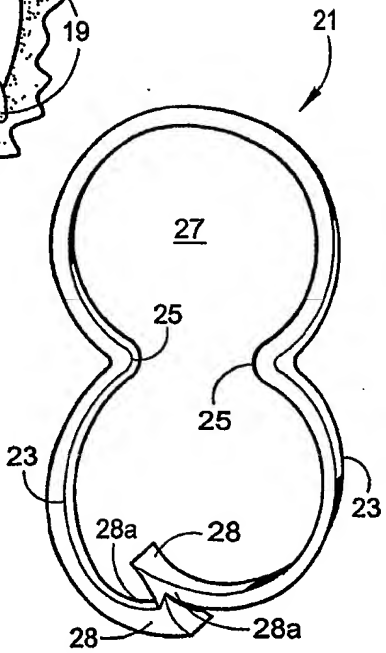


FIG. 5

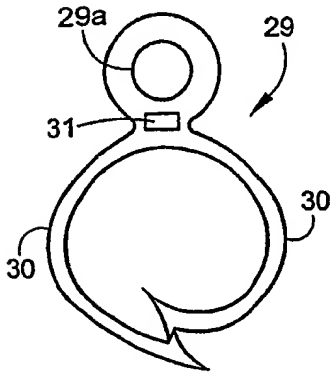


FIG. 5A

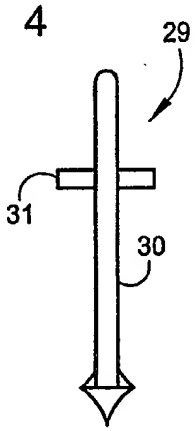


FIG. 5B

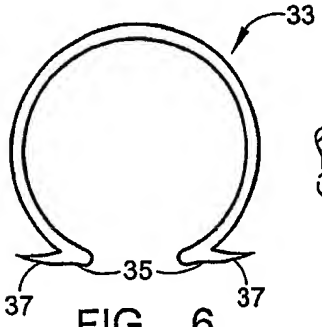


FIG. 6

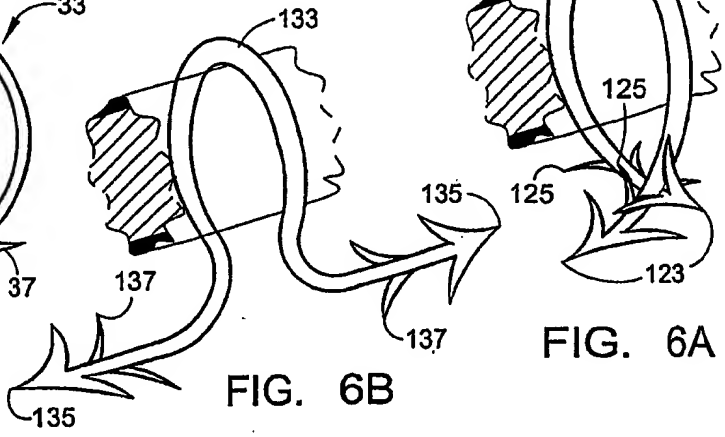


FIG. 6B

FIG. 6A

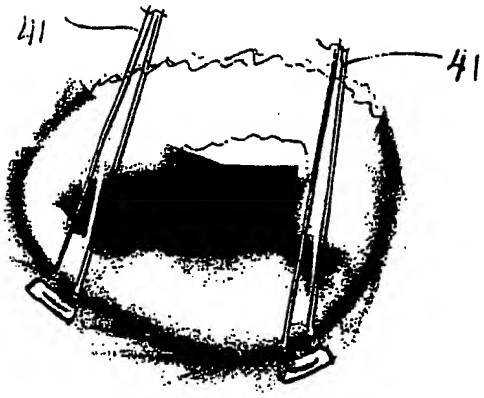


FIG. 7

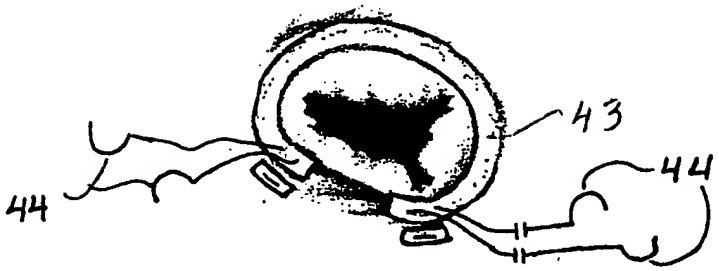


FIG. 8

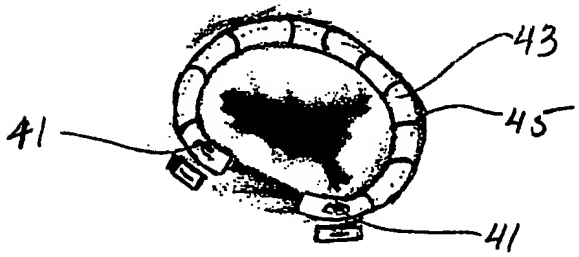


FIG. 9

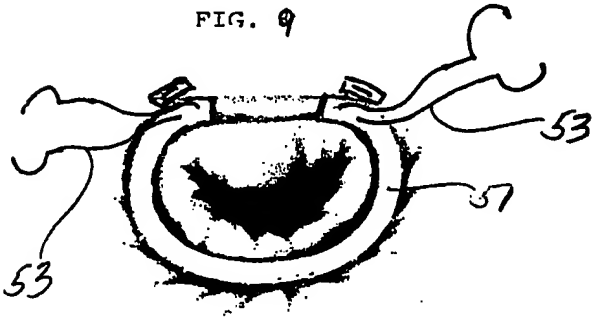


FIG. 10

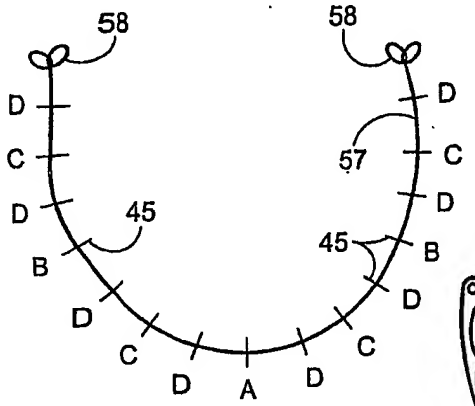


FIG. 11

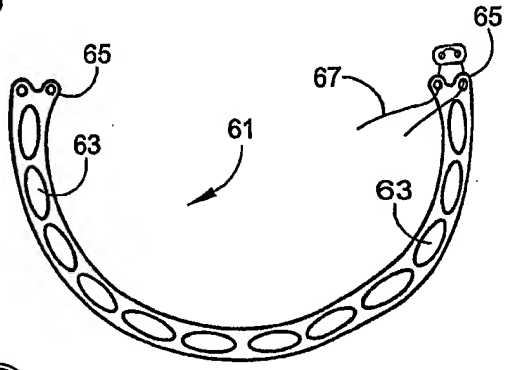


FIG. 12

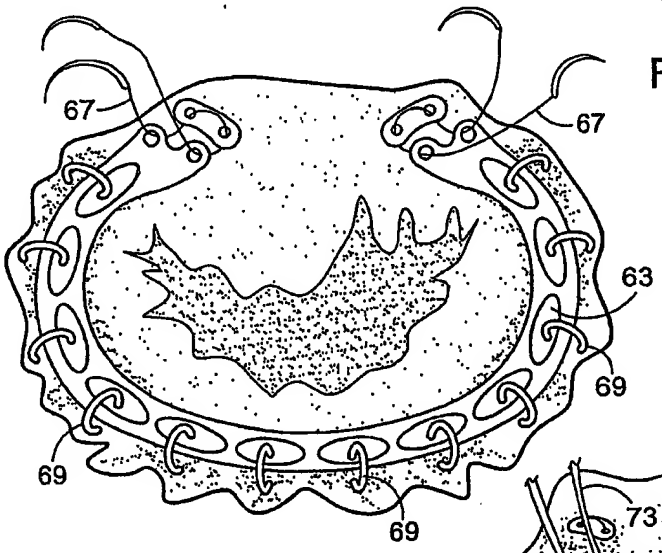


FIG. 13

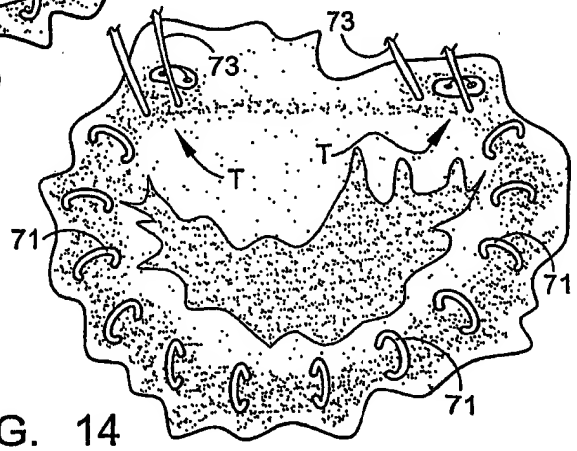


FIG. 14

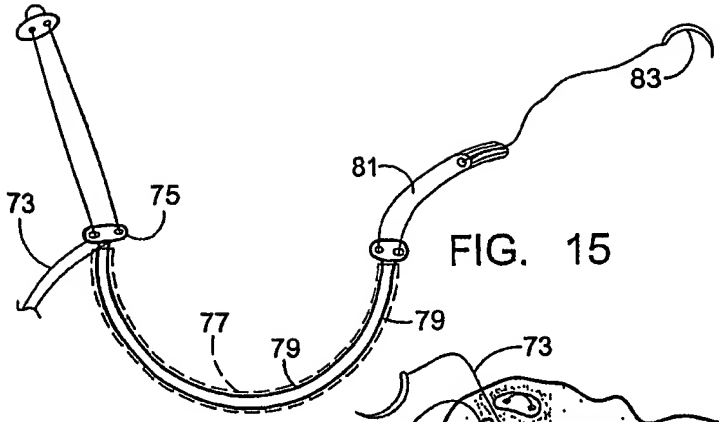


FIG. 15

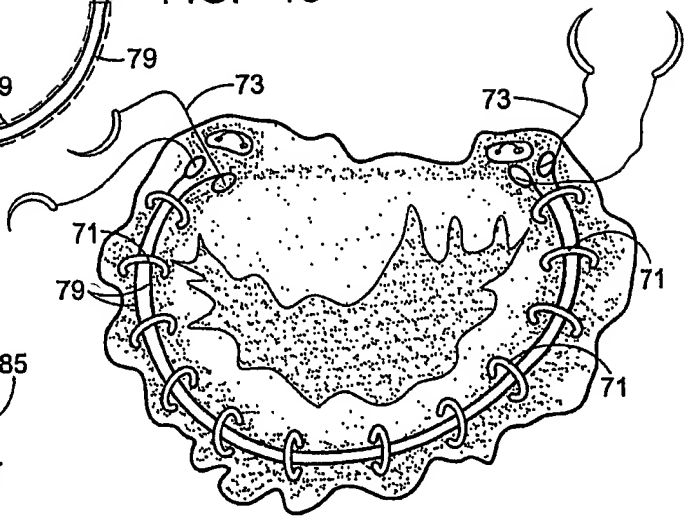


FIG. 16

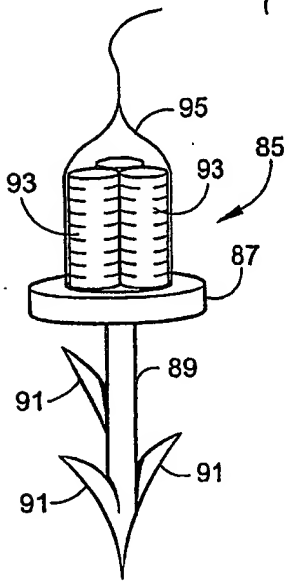


FIG. 17

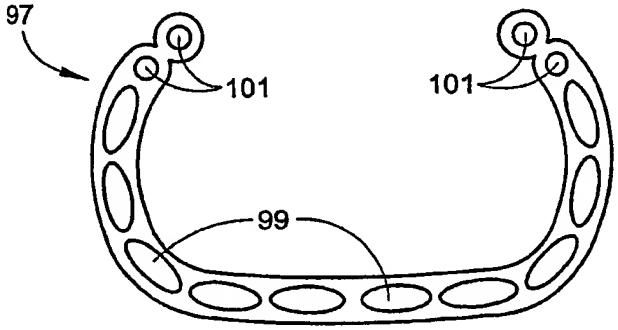


FIG. 18

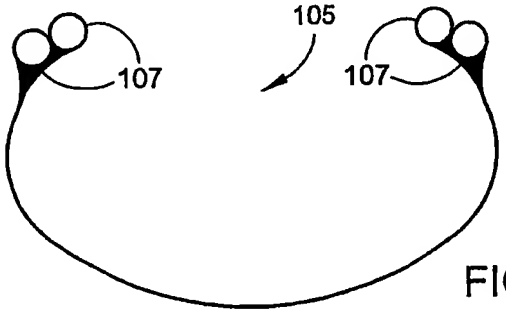


FIG. 19

FIG. 20

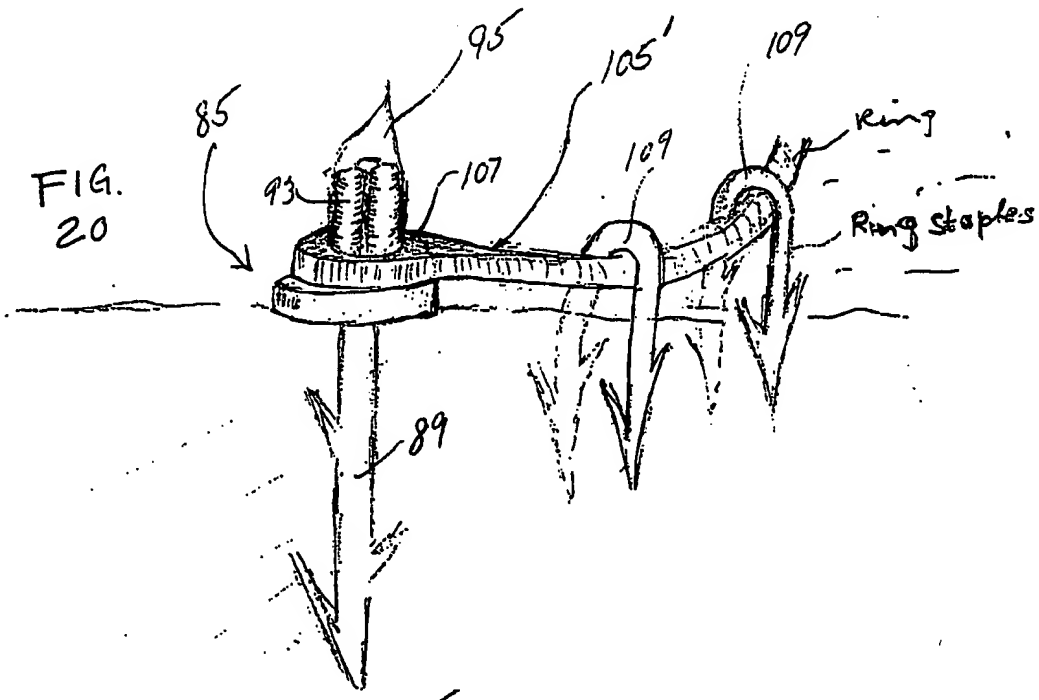


FIG. 21

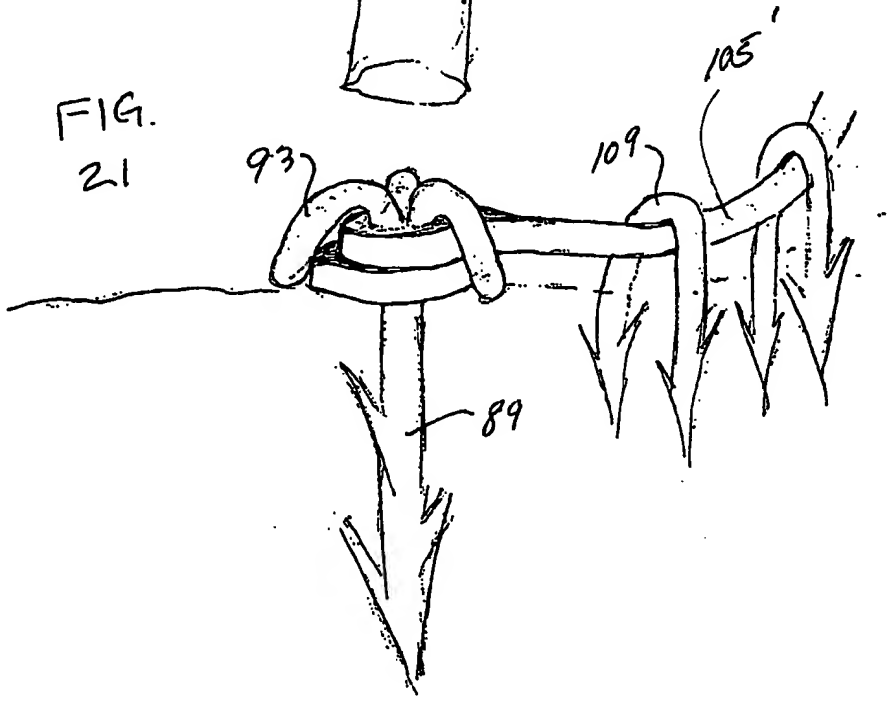
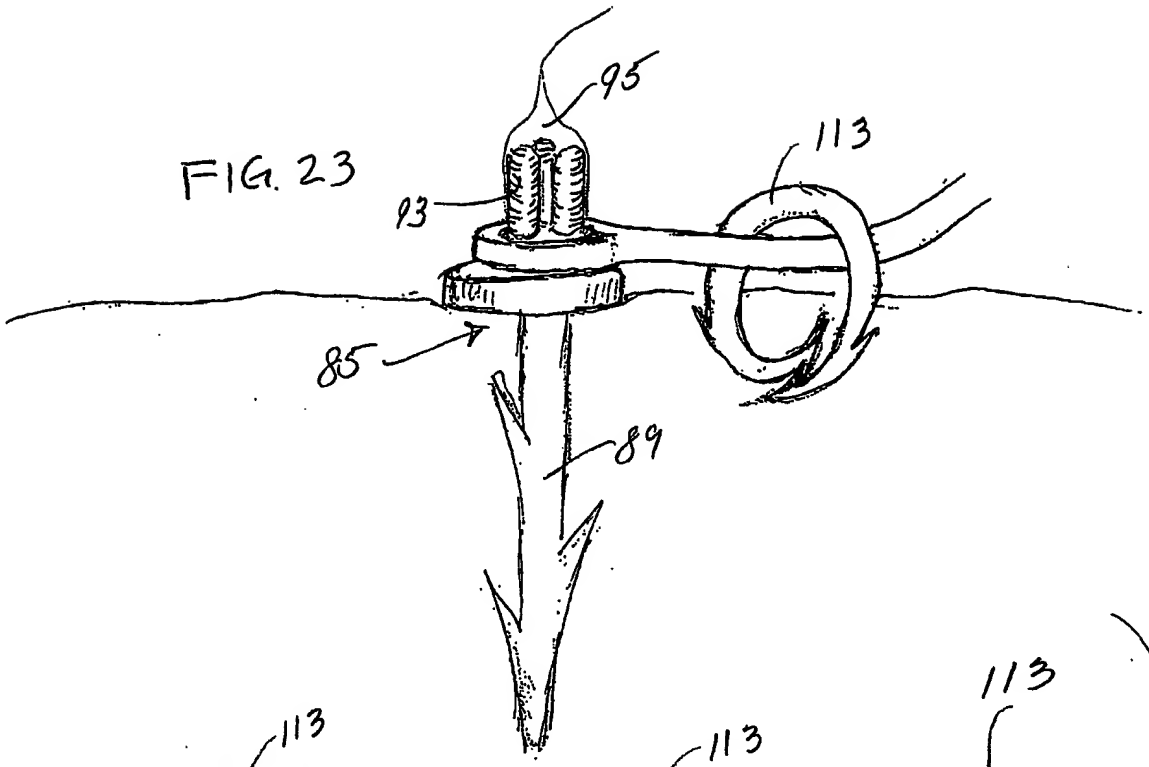


FIG. 23



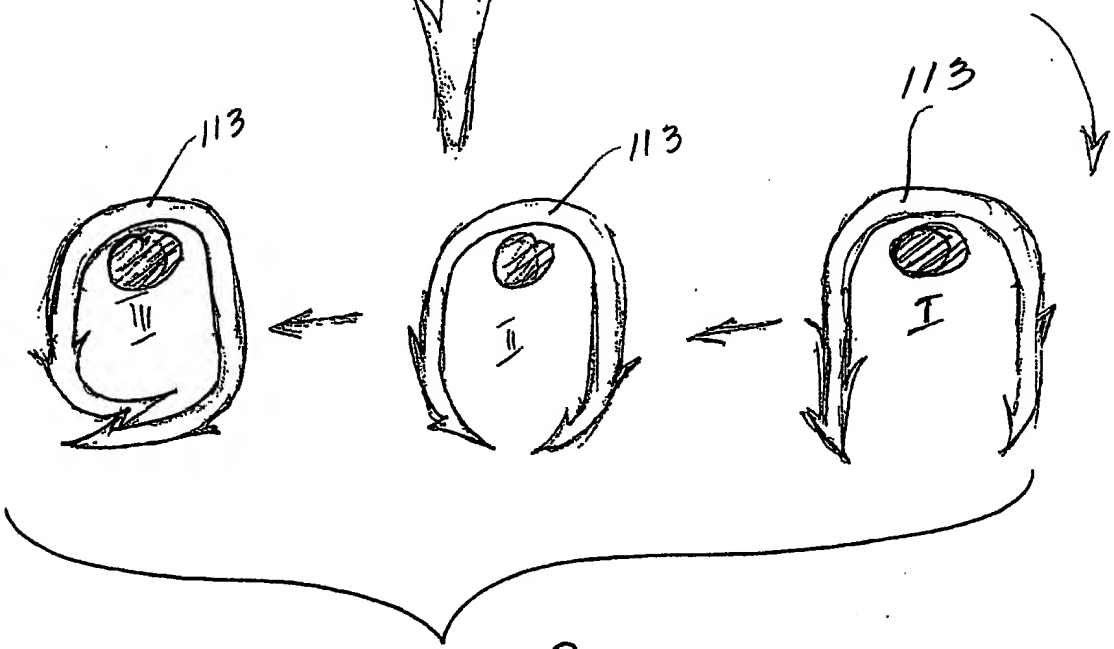


FIG. 22

INTERNATIONAL SEARCH REPORT

International application No.
PCT/IB02/05570

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) : A61F 2/24; A61B 17/064
US CL : 623/2.36; 606/151

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
U.S. : 623/904, 2.36, 2.4; 606/213, 215, 220, 232, 151

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 6,241,765 B1(GRIFFIN et al.) 5 June, 2001; Column 5, lines 31-59; Column 7, lines 13-	1
---	18; Column 4, lines 46-48; Column 3, lines 3-8; Figures 1, 6, 7	---
Y		2, 6-20
Y	US 6,106,550 A (Magovern et al.), column 3, lines 59-62; Fig. 1	15
Y	US 6,042,607 A' (WILLIAMSON, IV et al.) 28 March 2000, column 28, lines 8-31. Fig. 54A-54C; Column , lines 31-38.	11, 12
T	US 6,524, 338 B1Gundry) 25 Feb. 2003; Column 2, lines 49-52; Column 4, lines 16-30	1, 13
Y	US 6,007,557 A (Vanney et al.) 28 December 1999; column 6. lines 63-65.	1, 13

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent published on or after the international filing date

"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
15 April 2003 (15.04.2003)	20 MAY 2003
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No.	Authorized officer Michael J Milano Diane Smith for Telephone No. (703) 308-1148

Form PCT/ISA/210 (second sheet) (July 1998)